Recent Developments in Federal Tax, Antitrust and Fraud and Abuse Law

Over the course of the last couple of years, the National Association of Community Health Centers (“NACHC”) has published several Information Bulletins discussing various Federal laws and their impact on the development, structure and operation of Integrated Services Delivery Networks (“ISDNs”). In particular, ISDN Information Bulletins #4 - #6 — issued October 2002 — addressed the key elements and requirements of the Federal tax, antitrust and fraud and abuse laws, and explored structural and operational strategies under which ISDNs could achieve their desired goals and outcomes in an efficient and effective manner while maintaining compliance with such laws. Subsequently, in October 2003, NACHC issued ISDN Bulletin #8 (Recent Developments in Federal Tax, Antitrust and Fraud and Abuse Law), which provided an update in each of these areas, focusing on the legal developments that occurred since the publication of the initial bulletins.

This Information Bulletin represents the second legal update for ISDNs, addressing new developments that have occurred in the areas of Federal tax, antitrust and fraud and abuse law since the publication of Bulletin #8, and providing guidance with respect to how such developments may affect the network and its health center participants.1 Please note that this Information Bulletin is intended solely as an update in the law since the publication of the previous bulletins. As such, this document does not review the underlying laws and regulations specific to each area, nor does it provide background material regarding such laws.2

1 Please note that this bulletin does not provide specific legal advice with respect to any particular arrangement or activity, nor does it review or provide advice regarding specific State laws that are counterparts to the Federal laws discussed herein. Many States have laws similar to those discussed in this bulletin (as well as in previous bulletins), which must be carefully reviewed in conjunction with and in addition to all Federal requirements.

2 To obtain additional information regarding Federal tax, antitrust and/or fraud and abuse laws and their impact on ISDNs, please contact the NACHC Publications Department at (301) 347-0400 to request copies of the previously published ISDN Information Bulletins, or view the bulletins online at www.nachc.com under the Publications section.
FEDERAL INCOME TAX EXEMPTION

LEGAL DEVELOPMENT:

- The IRS and St. David’s Health Care System settle their case with St. David’s being permitted to retain its tax exemption.
- The IRS issues a ruling on so-called “ancillary” joint ventures between a tax-exempt organization and a for-profit entity.

Introduction

ISDN Information Bulletin #6 (Tax-Exemption Considerations In Structuring ISDN Affiliations Involving For-Profit Entities) and Information Bulletin #8 both discussed the Federal tax-exemption issues that may arise when a tax-exempt entity forms a joint venture with a for-profit entity. Tax-exemption issues will come into play when a tax-exempt ISDN entity affiliates with a for-profit entity. The tax-exemption of the exempt entity will be jeopardized if the tax-exempt “partner” cedes control of the joint venture to the for-profit partner. The recent developments discussed in this Information Bulletin have clarified the Internal Revenue Service’s (“IRS”) position with regard to joint ventures with for-profit entities.

Revenue Ruling (“Rev. Rul.”) 98-15

Rev. Rul. 98-15 was the IRS’s first formal guidance on the issue. There, the IRS held that the tax-exempt member of a joint venture must continue to operate exclusively in furtherance of its tax-exempt purposes. Further, the tax-exempt partner’s participation in the venture may not provide more than an incidental private benefit for the for-profit partner. In particular, Rev.Rul. 98-15 requires that the tax-exempt member of a joint venture with a for-profit entity must have an absolute majority, i.e., 51% voting authority, of the governing body of the joint venture.

St. David’s Health Care System Inc. v. United States of America

As reported in Information Bulletins #6 and #8, the application of Rev. Rul. 98-15 was challenged in litigation involving St. David’s Health Care System, a Texas hospital system that was tax-exempt under Section 501(c)(3) of the Internal Revenue Code (“IRC”). St. David’s lost its tax-exemption when it entered into a limited partnership with a for-profit health care system. St. David’s contributed all of its assets, primarily an acute-care hospital, to the venture and did not retain majority control of the venture’s governing body, as required by Rev. Rul. 98-15. The IRS revoked St. David’s tax exemption. However, St. David’s contended that there were numerous protections built into the joint venture agreement that prevented the inappropriate diversion of St. David’s charitable assets to the benefit of its for-profit partner. St. David’s argued that it had control of the joint venture “in fact,” notwithstanding the absence of majority voting control of the governing board of the joint venture.

St. David’s won its case in the Federal District Court, but the decision was overturned by the U.S. Fifth Circuit Court of Appeals, which sent the case back to the District Court for a trial on the merits. In March, 2004, a Federal jury held that St. David’s had, in fact, proved its case and reinstated its tax exemption. The litigation finally came to an end in June, 2004, when the IRS and St. David’s settled the case with St. David’s being permitted to retain its tax-exemption.

Both St. David’s and the IRS benefited from the settlement. The IRS avoided a potential judicial repudiation of the position it staked out in Rev. Rul. 98-15, while St. David’s retained its tax exemption. However, other organizations seeking to form joint ventures with for-profit organizations can draw little
guidance from the St. David’s litigation. It is clear, nonetheless, that the principles set out in Rev. Rul. 98-15 are very much alive with respect to joint ventures in which the tax-exempt partner contributes all, or a very substantial portion of its assets to the venture. Maintaining control of the venture remains the key to retaining tax exemption.

Rev. Rul. 2004-51

Perhaps the most productive result of the culmination of the St. David’s litigation was that it allowed the IRS to issue a much needed and long awaited ruling on so-called “ancillary” joint ventures between a tax-exempt organization and a for-profit entity. This type of joint venture, in which the tax-exempt organization contributes only a part of its assets to the venture, is much more common than the situation addressed in Rev. Rul 98-15. In Rev. Rul. 2004-51, the IRS addressed that situation for the first time in formal guidance.

In Rev. Rul. 2004-51, the parties had 50-50 control of the venture. The tax-exempt partner did not have a controlling interest that would satisfy the Rev. Rul. 98-15 test. Rev.Rul.2004-15 is significant because the IRS looked at whether participation in the joint venture amounted to a substantial part of the tax-exempt organization’s total activities instead of focusing on whether the tax-exempt organization controlled the joint venture. The IRS concluded that, even though the tax-exempt entity did not have majority control of the joint venture, its tax exemption would not be adversely affected since its activities with respect to the joint venture were not substantial. Moreover, any profit generated from the joint venture would not be subject to the unrelated business income tax (“UBIT”). Thus, the ruling increases the flexibility of tax-exempt networks and other tax-exempt organizations entering into joint ventures with for-profit organizations involving only part of the tax-exempt organization’s assets, as the tax-exempt entity will not have to insist on absolute control of the venture in order to preserve its tax exemption. However, the terms of any joint venture agreement should not permit the for-profit partner to control or otherwise to benefit from the assets of the tax-exempt organization that remain dedicated to tax-exempt purposes.

FEDERAL ANTITRUST LAW

LEGAL DEVELOPMENTS:

- The FTC adds more stringent reporting requirements to settlements with “messenger model” arrangements found to be in violation of Antitrust Law.
- The FTC and DOJ issue a report on the current workings of the health care marketplace.

Introduction

ISDN Information Bulletin #4 (Developments in Antitrust Law) provided an introduction to Federal antitrust law, including an overview of enforcement guidelines and methods by which collaborative arrangements are analyzed by the Department of Justice (“DOJ”) and the Federal Trade Commission (“FTC”), the agencies responsible for enforcing the Federal antitrust laws. In particular, Information Bulletin #4 reviewed various “safety zones” for arrangements and activities that, absent extraordinary circumstances, will be protected from antitrust enforcement, and explored other activities that may be conducted by actual or potential competitors, despite not satisfying the requirements of a particular safety zone.

Information Bulletin #4 and Information Bulletin #8 also explored certain agency actions in connection with the approval and/or disapproval of different network structures and various other network activities. This Information Bulletin discusses further developments in antitrust law pertaining to network development and operation, including, but not limited to, the joint publication of the DOJ and the FTC of the findings from a recent report on competition in the health care marketplace.

FTC Adds More Stringent Reporting Requirements to Settlements with “Messenger Model” Arrangements that are in Violation of Antitrust Law

As discussed in Information Bulletin #8, the FTC continues to successfully settle antitrust charges against provider networks that purport to engage in actions under messenger model arrangements, but, in actuality, serve as their respective members’ de facto exclusive bargaining agent with payors. Typically, under these scenarios, the FTC acts upon a determination that the network and its members have entered into agreements to engage in activities deemed “per se” violations of the Federal antitrust laws, including:

- Fixing prices and other competitively significant terms;
- Negotiating uniform fees/terms and entering into third party payor contracts on behalf of the members; and
- Refusing to deal with third party payors except on collectively agreed upon terms.

Often, the members will state an unwillingness to deal with payors except through their respective networks, and the networks will refuse to convey contract terms/offers to their members that the networks have deemed unacceptable. In some instances, a network may encourage its members to terminate their existing payor contracts, thereby forcing payors to deal exclusively through the network.5

Under such circumstances, the FTC typically determines that the illegal concerted actions unreasonably restrain trade and hinder competition for health care services by inflating fees and fixing other competitively significant terms of dealing with health plans (which, ultimately, results in harm to consumers). Accordingly, under the settlement agreements, the networks and their members are prohibited, directly and indirectly (through inducement of others), from:

- Entering into, participating in or facilitating any agreements to negotiate collectively, to deal (or refuse to deal) with specific payors, or to deal only through the network;
- Executing or facilitating any other agreement that fixes the terms of dealing; and
- Exchanging or facilitating the transfer of information among the members regarding an individual member’s willingness to deal and/or the terms and conditions on which the member is willing to deal.

Typically, the networks are not prohibited from engaging in conduct reasonably necessary to operate “qualified risk-sharing joint arrangements” or a “qualified clinically-integrated joint arrangements,” as defined by the settlements.

However, current trends indicate that the FTC is adding more stringent notice requirements should a network desire to initiate activities under a clinically (rather than financially) integrated approach, thereby allowing the FTC to review even seemingly permissible activities prior to their implementation. For example, on February 9, 2004, a settlement between the FTC and a preferred provider organization (“PPO”) operated by the Brown and Toland Medical Group (“Brown and Toland”) of California required Brown and Toland to give the FTC sixty (60) days prior notice before negotiating or entering into any agreement related to price or other terms of dealing under a qualified clinically-integrated joint arrangement.6

The Federal antitrust settlement agreements (including the Brown and Toland agreement) are not binding on any other parties. However, they are instructive to ISDNs and their participants in that they provide valuable guidance regarding the manner in which networks can implement joint activities for their participants, as well as the circumstances under which (and the extent to which) networks can act on their participants’ behalf, thereby reducing the likelihood that the ISDN and its participants will be subjected to allegations of antitrust violations.

5 Under all cases, the networks and their respective members did not engage in any “efficiency-enhancing” coordinated and/or integrated joint activity that could justify collective actions (i.e., the actions were not reasonably necessary to achieve or maintain clinical/financial efficiencies), nor did they claim to engage in such joint activities.

6 Similar to other settlements, for a period of five (5) years, Brown and Toland is also required to provide the FTC sixty (60) days prior notice before entering into any arrangement with physicians where it would act as a messenger on behalf of the physicians.
FTC and DOJ Issue a Report on the Current Workings of the Health Care Marketplace

On July 23, 2004, the FTC and the DOJ released a 361 page report entitled "Improving Health Care: A Dose of Competition," which provided much information on the current health care marketplace, but offered little in the way of new suggestions for health care providers on how to collaborate in ways that do not discourage competition.

Despite its lack of specificity, the following general advice may be helpful to health centers establishing ISDNs for the purposes of conducting joint negotiations and/or other joint activities.

Financial Integration

Information Bulletin #4 addressed the indicia of financial integration, which are used by the FTC and the DOJ to determine whether a physician network is sufficiently financially integrated for purposes of satisfying the integrated provider network safety zone (and, therefore, is able to avoid a “per se” violation of antitrust law). These indicia include:

- Capitation payments
- Global fee arrangements
- Fee withholds and
- Cost or utilization-based bonuses or penalties.

In the current report, the agencies added to the list of applicable indicia, indicating that, in making such determinations, they also will consider:

- The extent to which a particular “payment for performance” arrangement (i.e., an arrangement under which financial incentives are used to reward quality of care) constitutes the sharing of substantial financial risk among the participants.

Clinical Integration

As discussed in Information Bulletin #4, in 2002, the FTC issued its first (and, to date, only) advisory opinion permitting the establishment of a non-exclusive network based solely on clinical integration. In that opinion, the FTC determined that the proposed program facilitated and increased communication among the members, which, in turn, created both significant integration among their practices and certain efficiencies that could not be achieved by the members acting independently. In the report, however, the agencies declined to describe particular network structures under which providers would be able to achieve sufficient clinical integration to justify joint negotiations, stating their belief that listing specific structures could run the risk of channeling market behavior, rather than encouraging market participants to develop structures that are responsive to their own goals and the particular market conditions they face.

As an alternative, the agencies provided, by way of example, a list of questions that health care providers can utilize in self-assessing whether a particular arrangement may be sufficiently clinically integrated, including:

- What do the participating providers plan to do together from a clinical standpoint?
- How do the providers expect to accomplish these goals?
- What basis is there to think that the individual provider will actually attempt to accomplish the goals?
- What results can reasonably be expected from undertaking these goals?
- How does joint contracting contribute to accomplishing the goals?
- Is it necessary for providers to affiliate exclusively with one network, or can they effectively participate in multiple networks and continue to contract outside of the network?

Given both the report’s lack of specificity regarding the requirements for clinically integrated arrangements and the recent addition of stringent reporting requirements in settlement agreements prior to implementing such arrangements (as discussed above), ISDN participants should be cautious in relying solely on clinical integration as a basis to implement joint activities involving price and other competitively sensitive information, and are advised to seek specific approval from the FTC prior to implementing such joint activities.
FEDERAL FRAUD AND ABUSE LAW

LEGAL DEVELOPMENTS:

- Congress passes the health center safe harbor.
- OIG issues guidance for hospital discounts for the uninsured.
- DHHS Issues the Semi-Annual Regulatory Agenda.

Introduction

ISDN Information Bulletin #5 (Developments in Fraud and Abuse Law) provided an introduction to the Federal fraud and abuse laws (i.e., the anti-kickback law; Stark I and II, which prohibits physician self-referrals; and the False Claims Act), and explored strategies for structuring relationships between and among networks, their participants and/or third parties so as to reduce exposure under these laws. In particular, Information Bulletin #5 reviewed (1) the anti-kickback “safe harbors” under which, if all requirements are satisfied, an arrangement will be protected from prosecution under the Federal anti-kickback law, (2) other anti-kickback guidance issued by the Department of Health and Human Services (“DHHS”) Office of Inspector General (“OIG”) to facilitate the establishment and operation of such arrangements, and (3) the exceptions to the Stark law under which, if all requirements are satisfied, an arrangement will not be subjected to prosecution under Stark.

Information Bulletin #5 and Information Bulletin #8 also explored other guidance that, while not binding on the general public, provide direction as to current implementation and enforcement trends (i.e., advisory opinions, special fraud alerts and advisory bulletins, case law, and guidance related to corporate compliance and corporate responsibility). This Information Bulletin discusses further developments in fraud and abuse law pertaining to ISDN activities, including, but not limited to, the publication of final rules implementing certain provisions of the Stark II law.

Congress Passes the Health Center Safe Harbor

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003. This legislation included the long-awaited “health center safe harbor” to protect from prosecution under the Federal anti-kickback law certain arrangements between health center grantees and other providers/suppliers of goods and services that support or expand the availability and/or the quality of services provided to health center patients.7 Specifically, the safe harbor exempts from the definition of remuneration, which is prohibited by anti-kickback law:

any remuneration between a health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.8

7 Please note that the health center safe harbor applies only to health center grantees, and not to ISDNs in which health centers participate. Nevertheless, this safe harbor should provide a degree of protection from anti-kickback prosecution for arrangements between health centers and their ISDNs, as well as between and among the health center participants themselves.

8. Section 431(a) of H.R.1, the Medicare Prescription Drug and Modernization Conference Agreement.
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The legislation directs DHHS to establish standards relating to the safe harbor no later than one (1) year from the date of the legislation’s enactment (by December 8, 2004). In establishing the standards, the legislation requires that DHHS consider the following factors:

- Whether the arrangement between the health center and the other party results in savings of Federal grant funds or increased revenues to the health center.
- Whether the arrangement between the health center and the other party restricts or limits an individual’s freedom of choice.
- Whether the arrangement between the health center and the other party protects a health care professional’s medical judgment regarding medically appropriate treatment.

Recently, representatives from NACHC have consulted with officials from the OIG’s office to discuss issues related to the effective date and implementation of the safe harbor. An OIG official has informally advised NACHC that, in her opinion, the statutory safe harbor for health centers was effective as of the date of enactment of the statute (i.e., as of December 8, 2003).

At the present time, NACHC is awaiting a response to its request for a formal opinion as to the effective date.

The OIG official also indicated, however, that her views would not be binding on the DOJ. Further, the OIG official was unclear as to the type or extent of regulatory standards (other than those specified in the legislation) that the OIG’s office will establish to implement the statutory provision.

As such, until the regulations are issued, it is advisable that health centers proceed with caution when developing and implementing written agreements with actual or potential referral sources. In particular, we recommend the following:

- When negotiating appropriate arrangements with other providers, health centers should be mindful of the aforementioned statutory standards and, as necessary, consult with qualified counsel to minimize anti-kickback exposure.
- Health centers and their contracting partners should leave room to modify agreements as may be appropriate to secure safe harbor protection once the OIG issues the implementing regulations.
- Upon the publication of the regulations, health centers should review their contracts and, as necessary, amend the agreements to ensure compliance with the regulatory standards.

OIG Issues Guidance for Hospital Discounts for the Uninsured

On February 19, 2004, the OIG issued guidance clarifying that, under certain circumstances, hospitals have the ability to provide financial relief to uninsured and underinsured patients and Medicare beneficiaries who cannot afford their Medicare cost-sharing amounts, without running afoul of the Federal fraud and abuse laws.

Discounted Services

In particular, the OIG believes that neither (1) the Federal anti-kickback law, nor (2) the OIG’s authority to exclude from participation in Federal health care programs any provider that submits bills or payment requests to Medicare or Medicaid for amounts that are substantially more than the provider’s usual charges, prohibits or restricts hospitals from offering discounts to uninsured patients who cannot afford to pay their hospital bills. In the first instance, the Federal anti-kickback law prohibits a hospital from giving or receiving anything of value in exchange for referrals payable by a Federal health care program. However, it does not prohibit a hospital from discounting

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9 Further, DHHS may consider and include other standards and criteria that are consistent with Congress’ intent in enacting the health center safe harbor legislation.

10 CMS has also released a Q & A document, indicating that nothing in its regulations, Provider Reimbursement Manual, or Program Instructions prohibit the waiver or discount of charges to any patients, including low-income, uninsured, or medically indigent individuals, provided that waivers and discounts are made consistent with the hospital’s indigency policy (which should be used to determine a patients’ financial ability to pay for services). A person would be considered “medically indigent” if his or her insurance does not provide full coverage for all expenses and full payment of such expenses would result in the person becoming indigent.
the costs of services provided to uninsured patients who are unable to pay for such services, provided that the discounts are not linked to any business payable under a Federal health care program.\footnote{On the other hand, the OIG points out that discounts to underinsured patients may give rise to concerns, and, as such, hospitals should exercise care in providing such discounts, ensuring that there is no tie to business for which payment under Medicaid/Medicare is available.}

With respect to the OIG’s exclusive authority, the OIG pointed out that the statute contains an exception for situations in which the Secretary finds “good cause” for any substantial differences between the amounts billed to Medicare/Medicaid and the provider’s usual charges. Further, the OIG stated that the exclusion provision does not require a hospital to charge everyone the same, or to offer Medicaid/Medicare its best price, so long as the hospital does not routinely charge Medicare/Medicaid substantially more than it charges others.

Waivers of Cost-Sharing

The guidance also clarified that the Federal fraud and abuse laws do not prohibit hospitals from reducing or waiving Medicare cost-sharing amounts for patients experiencing financial hardships. Federal fraud and abuse laws prohibit (1) the routine waiver of cost-sharing in exchange for business payable by Federal health care programs and (2) the provision of inducements to Medicare/Medicaid beneficiaries in order to influence their selection of provider. However, the fraud and abuse laws also contain an exception to the waiver of cost-sharing obligations based on financial hardship, provided that the waiver is not advertised or routine, and it is determined in good faith that the person is in financial need (or reasonable collection efforts have failed).

Impact on ISDNs

Similar to the health center safe harbor, the clarifications contained in this guidance do not have direct impact on ISDNs. Further, in all likelihood, the guidance will not have a direct impact on an ISDN’s health center participants, which, by law, are required to provide discounts for low-income patients and, as such, are exempted from prosecution under a specific safe harbor for certain waivers of cost-sharing.\footnote{See 42 CFR § 1001.952(k)(2). This provision also exempts from prosecution a hospital’s waiver of cost-sharing for inpatient hospital services under specific circumstances.}

However, this guidance could make it easier for the health centers, or for ISDNs on their behalf, to enter into arrangements with other providers, under which the other provider furnishes discounted services to the health center’s patients eligible for sliding fee discounts.

DHHS Issues the Semi-Annual Regulatory Agenda

On June 28, 2004, DHHS issued its semi-annual regulatory agenda detailing all rulemaking actions currently under development or review. See 69 Fed. Reg. 37428. The agenda indicates that, by December 2004, we should see a final rule on the managed care shared risk safe harbor, which would provide an exception from potential anti-kickback liability for remuneration between an Eligible Managed Care Organization (“EMCO”) and an individual or entity (the “Provider”) providing items or services to the EMCO pursuant to a written agreement that places the Provider at “substantial financial risk” for the cost or utilization of the items or services provided.

If the Provider receives, in addition to payments from the EMCO, supplemental payments that effectively make it whole, such Provider would not satisfy the requirements of the proposed safe harbor. However, an exception is provided for health centers that receive wrap-around payments from the State Medicaid agency for services provided under Medicaid managed care arrangements, provided that the health center contracts directly with the EMCO. The proposed rule does not contain a similar exception to protect from prosecution arrangements under which the EMCO contracts with an ISDN or other intermediary, which, in turn, contracts with a health center receiving wraparound payments. In its December 2003 semi-annual report, the OIG indicated a willingness to modify this exception to include all health center managed care arrangements, regardless of whether the health center contracts directly with the EMCO or with an intermediary; to date, no such modification has been announced.
The Centers for Medicare and Medicaid Service ("CMS") Issues Final Stark Law Regulations

On March 26, 2004, CMS issued Phase II of the regulations designed to implement the Federal physician self referral law. See 69 Federal Register 15054. The regulations became effective on July 26, 2004. The statute, commonly referred to as the Stark law, applies to physician referrals of a patient to a health care entity with which the physician has a financial relationship (either an ownership interest or a compensation arrangement), if the referral is for one of 14 designated health services ("DHS"), (e.g. clinical laboratory services, radiology, inpatient hospital services), and the DHS will be paid for by Medicare or Medicaid. Unless the financial arrangement meets one of the specific exceptions in the statute and regulations, the entity providing a DHS cannot bill Medicare. For Medicaid patients, a State is not entitled to claim the Federal share of costs incurred in providing a DHS if the referral is prohibited by the Stark law.13

The Phase II final regulations culminate a rulemaking procedure that began in January, 1998. Phase I of the Stark Law regulations was published as a final rule in January 2001, and addressed statutory definitions and exceptions applicable to both ownership interests and compensation arrangements, added a few additional exceptions, and solicited comments on the rules as published. See 66 Federal Register 856, January 4, 2001, codified at 45 C.F.R. Part 424. Phase II, with a few notable exceptions, completes the regulatory process by addressing the statutory exceptions that were not covered in Phase I and by adding a few new exceptions.

Key Features of the Phase II Rules

Referrals for Medicaid-covered Designated Health Services

CMS deferred final rulemaking with regard to how it will apply the Stark law prohibitions to referrals for Medicaid-covered DHS, with one exception that will impact ISDNs operating a Medicaid managed care plan. The Phase II rules make clear that a referral of an enrollee in a Medicaid managed care plan for a plan-covered DHS is not subject to Stark. CMS gave no indication as to when regulations covering Medicaid referrals might be published.

Recruitment and Retention Incentives

CMS created two new exceptions specifically benefiting Federally Qualified Health Centers ("FQHCs"). The Phase II rules provide that a payment that an FQHC makes to a physician as a recruitment incentive and a payment made to retain a physician on the FQHC’s staff will not be considered to be “compensation” that would otherwise trigger the Stark Law’s referral prohibition, if the payment meets certain regulatory conditions. These exceptions may be significant for ISDNs that assist health centers in recruiting physicians. Note, however, that the exception applies to payments made by the FQHC only, not by the ISDN or other health care entity. (There is a separate Stark Law exception that applies to recruitment, but not retention, payments made by a hospital).

While each exception includes certain requirements that are specific to the respective exception, both exceptions require that:

- The arrangement between the physician and the FQHC be set out in writing;
- The arrangement not be conditioned on the physician’s referral of patients to the FQHC;
- The physician’s compensation not be directly or indirectly based on the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and
- The physician be permitted to refer business to any other health care entities, unless such referrals are restricted under a separate employment agreement that also complies with Stark requirements.

13 Unless an ISDN is appropriately licensed to provide clinical services or a DHS and either maintains a centralized clinical staff that includes physicians or directly provides the DHS for which it is licensed, in all likelihood, the Stark law would not have a direct impact on the ISDN’s operation. However, the Stark law may impact the operations of the ISDN’s participant health centers.
Recruitment exception – In addition to the general requirements discussed above, in order to be covered by the recruitment exception, the physician must:

- Relocate his or her practice into the geographic area served by the FQHC (defined as the lowest number of contiguous ZIP codes from which the FQHC draws at least 75% of its patients); and
- Physically relocate his or her practice at least 25 miles so as to be located within the FQHC’s service area, or at least 75% of the revenues generated by the recruited physician at the FQHC must be derived from providing services to patients not seen or treated by the physician at his or her previous medical practice site during the preceding three calendar years.

A “reasonable expectation” that the recruited physician will meet the 75% test during the initial year of practice with the FQHC is sufficient to satisfy the 75% test for the first year of a relocated physician’s practice with the FQHC. Residents and physicians who have been in practice one year or less do not have to meet the 75% test.

Retention exception – In addition to the general requirements discussed above, payments that an FQHC makes to retain the services of a physician will be protected if:

- The FQHC’s geographic service area is located in a HPSA or an area with a “demonstrated need” for the physician. Please note that a demonstrated need may be established only through a formal, written Advisory Opinion;
- The physician has a bona fide firm and written recruitment offer from a hospital or an unrelated FQHC, which specifies the remuneration being offered and requires the physician to relocate outside of the FQHC’s service area and at least 25 miles;
- The retention payment is limited to the lower of the difference between the physician’s current income and the income that the physician would receive if the physician accepted the bona fide recruitment offer, or the reasonable costs that the FQHC would otherwise have to expend to recruit a new physician to the FQHC’s geographic service area to replace the physician being retained; and
- The retention payment is subject to the same obligations and restrictions, if any, on the repayment or forgiveness of indebtedness as the bona fide recruitment offer.

An FQHC may not enter into a retention arrangement with a particular physician more than once every five years, and the amount or terms of the retention payment cannot be altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the retained physician.

Importantly, any recruitment or retention arrangement must not violate the Federal anti-kickback statute or any Federal or State law or regulation governing billing or claims submission. Accordingly, it will be important for ISDNs and their participants to analyze all aspects of any recruitment or retention arrangements before proceeding.

Percentage-based Compensation

The Phase II rules resolve the question of whether physician compensation based on a percentage of collections for services provided by the physician, which is common practice in the health care industry, meets the Stark law requirement that physician compensation be “set in advance.” As the total amount of compensation that a physician will receive under a percentage-based compensation arrangement can virtually never be determined beforehand, there was some question as to whether such payments are protected.

The Phase I regulations, published in 2001, essentially prohibited percentage-based compensation. However, as discussed in previous Information Bulletins, because of the controversial nature of the rule, CMS delayed the effective date of that particular provision four times.

The Phase II rule eliminates entirely the specific prohibition on percentage-based compensation. Rather, the final Phase II rule emphasizes that the formula for calculating percentage compensation (1) must be established prospectively, i.e., before the services are rendered, and with specificity, (2) must be objectively verifiable, and (3) may not be changed over the course of the time that compensation is paid to the physician based on the volume or value of referrals or other business generated by the physician.

While the Phase II rules permit percentage-based compensation for Stark Law purposes, it is important to remember that percentage compensation will not meet the “set in advance” requirement for safe harbor protection under the Federal

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anti-kickback statute and may attract Internal Revenue Service scrutiny if the compensation arrangement does not assure that the total compensation received is “reasonable” under all of the circumstances.

The OIG Issues a Second Educational Resource for the Boards of Directors of Health Care Organizations

As discussed in Information Bulletin #8, on April 3, 2003, the OIG issued an educational resource for Boards of Directors of health care organizations entitled “Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors.” The document provided an introduction to the Board’s fiduciary duty of care and indicated that, as part of its duty of care, the Board should be involved in the development, implementation and oversight of the organization’s corporate compliance program (including general supervision, control and oversight of management’s operation of the compliance program).

As a supplement to the first guidance, on July 1, 2004, the OIG issued a second educational resource for Boards, “An Integrated Approach to Corporate Compliance,” addressing the respective roles of in-house counsel and the corporate compliance officer in supporting the Board’s oversight authority (including each position’s reporting relationship with the Board), and the manner in which the two positions can be coordinated and integrated. The document poses several questions that the Board should pursue to ensure that (1) it understands the scope of the compliance program and, in particular, the roles of the in-house counsel and the compliance officer, and (2) the organization has processes in place to assure that the Board receives in a timely manner appropriate information and candid assessments in connection with the compliance function.

Of note, the document discusses the recently amended Federal Sentencing Guidelines (which provide the framework for corporate compliance programs, in general), which indicate that, to be effective, the compliance officer must hold a high level position within the organization that encompasses substantial control or a substantial policy-making role. Further, the compliance officer (or other individuals responsible for daily operations of the compliance program) must: (1) have direct access to the Board of Directors, and (2) provide reports to the Board at least annually. Accordingly, whether an ISDN or a health center chooses to combine compliance functions with another position, or to maintain them as a separate position, the responsible individual should be part of the organization’s key management team.

Although the principles outlined in both OIG guidances are voluntary in nature, with the recent multitude of Federal and State corporate responsibility legislation and guidance, it is advisable for ISDNS and their participant health centers to develop and implement corporate compliance programs, and to review and discuss with their respective Boards the issues addressed in the guidances.

CONCLUSION

As recipients of Federal grant funds, ISDNS and their health center participants are subject to a variety of Federal laws, regulations and policies impacting, among other things, their establishment, governance, and operation. Three key areas that require significant consideration are the Federal tax, antitrust, and fraud and abuse laws. This Information Bulletin addresses legal developments that have occurred in each of these three areas during the past year, and provides guidance with respect to how such developments can be applied to minimize exposure for the ISDN and its participants while maximizing effectiveness.